Amendments to the Drawings:

Filed herewith are three (3) replacement sheets of drawings which contain changes to Figs. 2A, 2B and 2C. These sheets replace original sheet(s) 2/7, 3/7& and 4/7.

REMARKS/ARGUMENTS

By the foregoing amendment, the drawings and claims 1, 16, 25, 29, 33 and 34 have been amended. Claims 2-4, 23 and 26 have been cancelled and new claims 36 and 37 have been added. Thus, following entry of this amendment, claims 1, 5-22, 24, 25 and 27-37 will be pending. No new matter has been added. Reconsideration is respectfully requested.

Allowable Subject Matter

In the Office Action, the subject matter of dependent claim 23 was deemed allowable. Accordingly, independent claim 16 has now been amended to include limitations that substantially parallel those of allowed claim 23 and claim 23 has been cancelled. Thus, claims 1-22 and 24 are believed to be in condition for allowance.

Rejections Under 35 USC §102/§103

Independent claims 1 and 25 have been amended to recite further details of the bymixer device. Amendments have also been made to dependent claims 29, 33 and 34 to correct minor typographical errors and/or to comport with the amended language of the independent claim.

A non-limiting example of the claimed bymixer device is shown in Figure 2C, reproduced below:

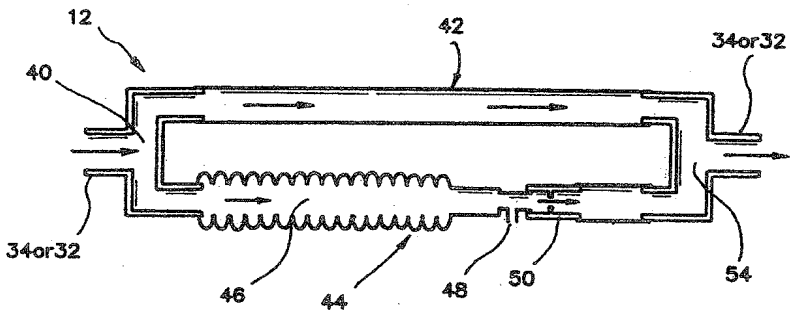

FIG. 2C

With reference to the example of Figure 2C, the presently claimed bymixer device has an inflow port (i.e., the opening at the left end of the device) that is connected to a conduit such that all respiratory gas flowing through that conduit enters the inflow port. A flow divider (40) then divides the flow of respiratory gas that enters the inflow port into first and second streams. The

first stream flows through a main flow channel (42). The second stream flows through a bypass flow channel (44). The bypass flow channel (44) includes a flow restrictor (50) and a mixing chamber (46) upstream of the flow restrictor. The mixing chamber (46) comprises tubing that is alternately extendable and contractible so as to enable a user to alternately increase and decrease the volume (i.e., the interior volume) of the mixing chamber and sampling apparatus (48) for sampling respiratory gas from said mixing chamber. In some embodiments, the sampling apparatus may be a port through which a sample bay be withdrawn. In other embodiments, the sampling apparatus may comprise a sensor for sensing gas within the sampling chamber. As the first and second streams exit the main flow channel (42) and bypass flow channel (44), a flow combiner (54) combines the first and second streams to form a combined outflow stream. An outflow port (i.e., the opening at the right end of the device) is connectable to a conduit (e.g., a downstream segment of the same conduit to which the inflow port is connected) such that the combined outflow stream enters that conduit.

The cited prior art references do not teach or suggest the presently claimed bymixer device or its novel method of use.

With respect to United States Patent No. 6,196,222 (Heinonen) the Office Action specifically cites Figure 3, which is reproduced below:

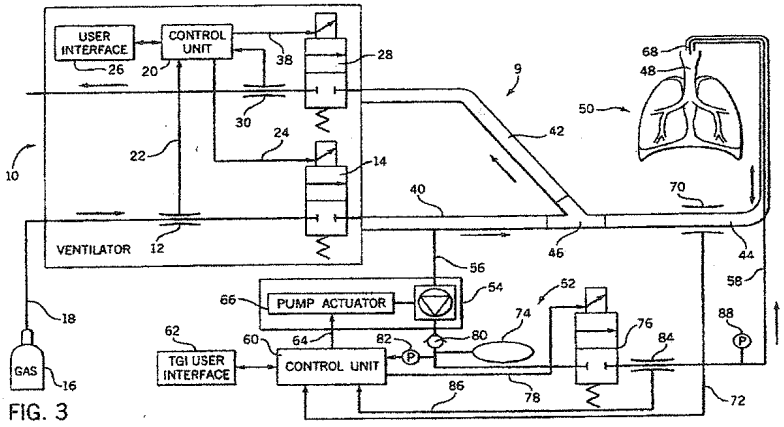

FIG. 3

Heinonen describes his Figure 3 as follows:

> In the synchronized form of the TGI delivery system shown in FIG. 3, the delivery takes place only during about one third of the breathing cycle. In order to get enough volume in the TGI delivery within this relatively short period of time, the TGI flow generating unit 52 may be arranged to pressurize an intermediate cylinder 74 that is connected to the delivery line 58 as shown in FIG. 3. The volume of the intermediate cylinder 74 is advantageously 0.5-3 dl. To facilitate TGI delivery, the delivery line 58 is also equipped with a flow control valve 76 that is controlled by the control unit 60 through a control line 78. The flow control valve 76 may be either a digitally controlled on-off type or a proportionally controllable valve for various flow rates. In the embodiment shown in FIG. 3, the TGI flow generator 54 may run either continuously or intermittently. When running intermittently, the flow path from the intermediate cylinder 74 backwards through the TGI flow generator 54 to inlet line 56, is equipped with a check valve 80 to prevent the back flow of gas from the intermediate cylinder 74. Although the check valve 80 is shown as a separate component, such check valves 80 are often an inherent feature found in many pumps, which can be advantageously used. In the embodiment shown in FIG. 3, the control unit 60 also has the capability to control the flow control valve 76 through the control line 78.
>
> The delivery line 58 upstream from the flow control valve 76 may also be equipped with a pressure sensor 82. The pressure measured by the pressure sensor 82 reflects the pressure of intermediate cylinder 74 and may be used by the control unit 60 for controlling the cylinder loading. By regulating the system

pressure, the TGI delivery flow, and thus the volume of gas delivered, can be regulated. If the TGI flow generator 54 ceases loading the intermediate cylinder 74 for the dosing period, the TGI flow and delivered volume can be deduced from the intermediate cylinder volume and the pressure difference occurring under the dosing.

The delivery line 58 may also be equipped with a flow sensor 84 for the TGI flow measurement. The flow sensor 84 is coupled to the control unit 60 through a data line 86. When the flow control valve 76 is a proportional valve, the flow sensor 84 can be utilized to regulate the TGI to a predefined flow rate. The plurality of sensors and devices in communication with the control unit 60 add to the functionality of the control unit 60 and possibly to the TGI user interface 62 in the form of different possible informational displays.

In the embodiment of the breathing system shown in FIG. 3, a pressure sensor 88 is positioned downstream from the flow control valve 76. When little or no flow is present in the delivery line 58, the pressure measured by the sensor 88 equals the pressure at the outlet of the delivery line 58. When the outlet of the delivery line is located in the distal end of the endotracheal tube 68, as in FIG. 2, the measured pressure at sensor 88 is approximately the airway pressure. A problem with conventional airway pressure measurement has been occlusion of the pressure measuring tube in the airway due to patient excretions, like mucus and moisture. In the TGI delivery system shown in FIG. 3, this problem is avoided since the delivery line 58 is flushed open with the TGI gas dose. TGI delivery system 52 thus provides a convenient, reliable way to obtain airway pressure measurement.

> Ventilators 10 of current manufacturer typically by a special operation sequence stop the exhalation flow for measurement of the airway pressure.

Clearly, the circuit shown in Figure 3 of Hienonen fails to include the presently claims bymixer device or anything similar to it. In the Office Action, the Examiner contends that item Heinonen's item 74 is a "mixing chamber" and that item 84 is a "sampling apparatus" for sampling gas from the mixing chamber. In reality, item 74 is described as an "intermediate cylinder" and item 84 is described as a "flow sensor." A flow sensor measures flow rate, it does not sample gas and it cannot be used to measure a component of the respiratory gas as claimed by applicant. Thus, the claims as presently amended are novel and unobvious over Heinonen.

United States Patent No. 4,619,269 (Cutler et al.) describes an apparatus and method for monitoring respiratory gases in newborn infants. The apparatus includes a first fluid flow circuit from which an oxygen enriched gas is used to ventilate the patient, and a second fluid flow circuit connected in parallel to the first circuit. The second fluid flow circuit is used to isolate respiratory gases expired by the infant so that the respiratory gases can be accurately monitored for concentrations of the carbon dioxide and oxygen, which are then used to calculate metabolic rate and other clinical data used in properly caring for the patient. The apparatus also includes electronic processing capability for quickly determining the needed data and for outputting it in a format which is convenient and readily available for use by doctors, nurses or technicians. Cutler et al. fails to describe any bymixer having a main flow channel and a bypass flow channel that includes; 1) a flow restrictor that restricts the flow of gas through the bypass flow channel, 2) a mixing chamber upstream of the flow restrictor, such mixing chamber comprising tubing that is alternately extendable and contractible to enable a used to alternately increase and decrease the volume of the mixing chamber and 3) sampling apparatus for sampling respiratory gas from said mixing chamber. Thus, the present claims are patentably distinguishable over Cutler et al.

The three (3) sheets of replacement drawings contain reference numeral changes which overcome the drawing objection stated in the Office Action.

An Information Disclosure Statement and a substitute declaration will be filed separately from this response.

Conclusion

Thus, for the foregoing reasons and possible others not specifically articulated here, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any fees due in connection with the filing of this paper to Deposit Account No. 50-0878. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, the Examiner is encouraged to telephone Applicant's counsel.

Respectfully submitted,

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